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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/730,421      | 12/08/2003  | Henry Nita           | PAT-1540            | 2510             |

7590 09/08/2006  
Raymond Sun  
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EXAMINER

VRETTAKOS, PETER J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3739

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                |                             |  |
|------------------------------|--------------------------------|-----------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/730,421  | Applicant(s)<br>NITA ET AL. |  |
|                              | Examiner<br>Peter J. Vrettakos | Art Unit<br>3739            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.  
 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-27 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 17-27 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

**The action is final. RCE filed 8-21-06.**

**Claims 17-27 are pending. (Claims 28-29 seemed to have been truncated from prosecution. Clarification is required.)**

**A revised figure 1 was allegedly submitted by the Applicant, however the Examiner cannot locate the figure in the record as of 9-2-06. The Applicant is requested to resubmit.**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 17-18, 20-21, 23, 25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaer et al. (6,522,930).**

#### **Independent claim 17**

Schaer discloses a method of placing the distal end of an ultrasound (col. 2:46-51) catheter at a desired location inside a vessel, comprising:

providing a sheath (124, figures 14-15) having an elongate body that has a lumen and a distal end;

providing a guidewire (col. 12:55-61);

extending the ultrasound (col. 2:46-51) catheter (130) over the guidewire (col. 12:55-61) through the lumen of the sheath (124); and

extending the sheath (124) through the lumen of a guide catheter (col. 4:20-31).

Dependent claims (below numbers correspond to claims)

18 and 19. The method of claim 17, further including: advancing and retracting the sheath (124) independently beyond the distal end of the ultrasound catheter (130). These steps are depicted in time sequential figures 14 and 15.

20. The method of claim 17, further including: torquing (see double-sided arrow at the distal end of the sheath in figure 15) the sheath to redirect the angled distal end of the sheath.

21. The patented sheath (124) includes an outer polymeric material (multiple tubings, col. 25:52) with a reinforcing layer (laminated braided structure, col. 25:53-55).

23. The distal shaft member (134, figure 15) has a smaller outer diameter than the main shaft member.

25. Excluding the porous membrane 132 in element 124 of figures 14 and 15, the drawings depict uniformity stingly inferring that 124 the distal shaft member 134 is of equal hardness to 124 (the main body of the sheath).

27. Element 124 (distal end, figure 15) is angled within the claimed dimensions.

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**1. Claims 19, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer et al. (6,522,930) in view of Kesten (6,251,104).**

Schaer discloses:

19. The method of claim 17, further including: retracting the sheath (14) proximal from the distal end of the catheter (16). The same reversal rationale applies here. The patent discloses advancing and retracting the catheter relative to the sheath. *In re Gazda* indicates these differences between the patent and the Applicant's claims as obvious.

*Schaer is silent with respect to lubricious coatings.*

Regarding claims 22 and 26, in an analogous device, Kesten discloses an elongate body (14/26; figure 2) with lubricious coatings. Lubricious coatings 27 and 30 both lie in inner surfaces of elements 14 and 13. According to MPEP 2144.04 VI. A., which is presented below, the reversal is obvious. Note also that the reversal here

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yields the same ends/result, to lubricate/facilitate movement of the two parts providing the motivation to combine the patents.

## **VI. REVERSAL, DUPLICATION, OR REAR-RANGEMENT OF PARTS**

### **A. Reversal of Parts**

*In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient.).

**2. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer et al. (6,522,930) in view of Berg et al. (5,680,873).**

Schaer et al. (6,522,930) *is silent regarding a lack of reinforcements in the polymeric material.*

Berg discloses an analogous device that propounds the advantages (col. 5:9-14) of reinforcement free polymeric material in the context of the patented device such as cost.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Schaer et al. (6,522,930) in view of Berg by leaving out reinforcing material. The motivation would be to keep costs of manufacturing down (Berg col. 5:9-14).

***Response to Arguments***

Applicant's arguments filed 8-21-06 have been fully considered but they are not persuasive. The Applicant argues that no guidewire is disclosed directly corresponding to Schaer's invention in figures 14-15. However, this does not obviate the above rejections. The patent mentions in col. 25:44-45 that the invention in figures 14 and 15 is a variation of the tissue ablation assembly disclosed throughout the patent. The tissue ablation assembly disclosed in figure 1 includes a guidewire lumen (22) thereby inferring the presence of a guidewire. See corresponding disclosure in col. 12:55-61. The Office asserts that element 130 in figures 14 and 15 is directly analogous to element 16 in figure 1 **including** the guidewire lumen (22) and therefore, the invention in figures 14-15 can be read to include a guidewire notwithstanding the fact that the invention in figures 14-15 can potentially be without a guidewire. The Examiner is not simply "cobbling" "bits and pieces" from the patent, but is applying commonsensical arguments to prosecution. It's noted that the increasing complexity of the electrosurgical arts yields many patents of this type, which include numerous embodiments with different elements. It is fully appropriate to intermix different elements from different embodiments seamlessly unless doing so destroys the operation of one of the embodiments. Patented inventions cannot be viewed in a vacuum and most certainly different embodiments within a patent cannot be viewed in a vacuum (separate from each other). Doing so would require an inventor in a patent to disclose every element in every embodiment is every possible combination, which would yield inappropriately long disclosures. This rationale also addresses the Applicant's argument that the assembly in figure 1 has no sheath. (The embodiments in a patent are seamlessly

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interchangeable unless intermixing destroys an embodiment's function.) As such, the rejections are not hindsight reconstruction and are appropriately maintained.

The Applicant argues that the relevance of col. 4:20-31 is unclear. The Office asserts that regardless of the fact that the language is not directly toward the Schaer invention, **it is part of the Schaer patent**. The disclosure is relevant because it is centralized with the Schaer invention. It is part of the prior art disclosure. The fact that it is not directly related to the Schaer invention (because it is part of the background section) is wholly irrelevant. The Applicant is picking specific excerpts from the patent and viewing each excerpt in a vacuum, separate from the rest of the patent. Doing so is ineffective as the excerpts are to be read in the context of the entire patent and not solely what the Applicant defines as the boundaries of what should be considered.

The prior 35 USC § 112 rejection is obviated through clarifying arguments dated 8-21-06.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos  
September 1, 2006

  
ROY D. GIBSON  
PRIMARY EXAMINER